EXHIBIT K

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
GREENEVILLE DIVISION

UNITED STATES OF AMERICA and STATE OF TENNESSEE, *Plaintiffs*, v. WALGREEN CO., *Defendant*.	Case No. 2:21-CV-00080-JRG-CRW

PLAINTIFFS' RESPONSES TO DEFENDANT'S SECOND REQUESTS FOR PRODUCTION OF DOCUMENTS

Plaintiffs United States of America and State of Tennessee (collectively, "Plaintiffs" or "the government") hereby tender these Responses to Defendant Walgreen Co.'s ("Walgreens" or "Defendant") Second Requests for Production of Documents.

GENERAL OBJECTIONS TO ALL DEFINITIONS, INSTRUCTIONS AND REQUESTS

These responses are made solely for the purpose of this action. The responses, including any production of documents, are subject to the terms and conditions of any protective order(s) entered in this action, and certain documents shall be withheld from production pending the entry of an appropriate protective order.

Plaintiffs object to these Requests to the extent they seek to impose upon the government any requirements beyond those established by the Federal Rules of Civil Procedure, the Local Rules of the United States District Court for the Eastern District of Tennessee, or any order of the Court.

Plaintiffs' investigation of the facts is on-going. Accordingly, the following responses are

given without prejudice to their right to produce subsequently discovered material, and Plaintiffs reserve the right to supplement these responses pursuant to Rule 26(e), Fed. R. Civ. P.

By these responses and production of documents, Plaintiffs do not waive, and hereby expressly reserve, their right to assert any and all objections as to the admissibility of any documents, testimony, or information into evidence in this action, or in any other proceedings, on any and all grounds including, but not limited to, competency, relevancy, materiality, privilege, or admissibility. Further, Plaintiffs make responses and objections herein without in any way implying that they consider the documents requested to be relevant or material to the subject matter of this action. No admission of any nature is to be implied or inferred from these responses.

Plaintiffs reserve the right to assert privilege for any privileged document that is inadvertently produced in response to these requests for production of documents. In the event such documents are inadvertently produced, such production by Plaintiffs of a document containing attorney-client communication, attorney work-product or otherwise privileged information shall not constitute a waiver of privilege and such document or documents shall be returned to Plaintiffs immediately upon request. Included in this reservation are not only documents promulgated by Plaintiffs but also any documents produced by Plaintiffs that may have been promulgated by others.

Pursuant to Federal Rule of Evidence 502, Federal Rule of Civil Procedure 26(b)(5)(B), other related sources of law, and the protective order which the parties intend to seek, Plaintiffs reserve any and all rights to seek the return, sequestration, or destruction of any and all privileged information inadvertently produced in response to the requests.

Plaintiffs object to these Requests to the extent that they seek documents that are in the possession, custody, or control of Defendant, because such documents are at least equally available

to Defendant as they are to Plaintiffs. Plaintiffs also object to these Requests to the extent that they seek documents that can be obtained in a more convenient and less burdensome manner from some other source (including, but not limited to, a public source).

When Plaintiffs respond that they will produce documents in response to a Request, they will produce non-privileged documents to the extent that such documents exist and can be identified through a reasonable search of files and other repositories likely to contain responsive material. By stating that they will produce documents, Plaintiffs do not represent that responsive, non-privileged documents in fact exist, or that they are within its possession, custody, or control, but rather state that they will undertake a reasonable search for responsive documents and will produce any responsive, non-privileged documents identified by that search. Further, to the extent that any Request pertains to "communications" within the relevant time frame, production of non-privileged/non-protected documents will require a list of search terms as agreed upon between adversary counsel.

The United States of America asserts the investigative files and law enforcement privileges, and the attorney work-product privilege, with regard to the investigative files of the Tennessee Bureau of Investigation and the contents thereof. *See In re Green Grand Jury Proceedings*, 492 F.3d 976 (8th Cir. 2007); *In re Dep't of Investigation*, 856 F.2d 481 (2d Cir. 2007). Accordingly, Plaintiffs shall not disclose the substance or content of these files.

The specific responses to each Request for Production incorporate each of the General Objections set forth above and the Specific Objections to Definitions and Instructions set forth below. These Objections are included here to avoid duplication and needless repetition. These Objections form a part of each specific Response and the failure to reference these Objections in a particular Response does not waive any of the Objections.

SPECIFIC OBJECTIONS TO DEFINITIONS

Plaintiffs object to the definition of "Plaintiffs" as including "any agency, bureau, department, component, program, office, or authority within the government of either of them, and includ[ing] counsel for any such agency, bureau, department, component, program, office, or authority within the government of either Plaintiff." This definition is overly and unreasonably broad, such that it includes any and all federal or state agencies, including the numerous governmental agencies not relevant to the claims or defenses in this matter. Plaintiffs contend that the only departments and agencies relevant to this case are those whose area of responsibility include administration of the TennCare/Medicaid pharmacy benefit or investigation and litigation of civil False Claims Act cases. Consequently, the Plaintiffs construe the definition of "Plaintiffs" to mean only the United States Attorney's Office for the Eastern District of Tennessee; the Office of the Attorney General for the State of Tennessee; the Tennessee Bureau of Investigation, Medicaid Fraud Control Unit; the Department of Health and Human Services (HHS); and the Tennessee Department of Finance and Administration.

Plaintiffs object to the definition of "Four DAAs" as including "one *or more* of the following direct-acting antiviral medications to treat Hepatitis C: Harvoni®, Sovaldi®, Daklinza®, and Viekira Pak®." The definition is overly and unreasonably broad, as well as self-contradictory. Consequently, Plaintiffs construe the definition of "Four DAAs" to mean only Harvoni®, Sovaldi®, Daklinza®, and Viekira Pak®, singularly or jointly and regardless of dosage or method of administration.

Plaintiffs object to the definition of "Magellan" as including "any parent, subsidiary, affiliate, predecessor or successor entity of it, any department or business unit of any such entity, and any employee, attorney, agent, advisor, investigator, or representative of any of the foregoing."

The definition presumes comprehensive knowledge on the part of Plaintiffs of the corporate structure of Magellan Medicaid Administration, Inc., which Plaintiffs specifically disclaim.

Plaintiffs object to the definition of "OptumRx" as including "any parent, subsidiary, affiliate, predecessor or successor entity of it, any department or business unit of any such entity, and any employee, attorney, agent, advisor, investigator, or representative of any of the foregoing." The definition presumes comprehensive knowledge on the part of Plaintiffs of the corporate structure of OptumRx, Inc., which Plaintiffs specifically disclaim.

Plaintiffs object to the definition of "You" as including Magellan and OptumRx. By contract, Magellan Medicaid Administration, Inc., and OptumRx, Inc., are deemed independent contractors to the State of Tennessee, and any agency relationship is specifically disclaimed by the terms of their respective contracts (which were submitted to CMS for review and approval). Plaintiffs further object to the inclusion of OptumRx in the definition of "You," as the facts at issue all pertain to the period of time at which Magellan functioned as the Pharmacy Benefits Manager of TennCare, and prior to the commencement of OptumRx as the PBM for TennCare on January 1, 2020. Notwithstanding this objection as it relates to Magellan and OptumRx, Plaintiffs will continue to request information from such entities and will recite accurately and faithfully the information received from those entities in the applicable responses below.

RESPONSES

31. Documents and data reflecting all offsets to sums paid by TennCare for prescriptions for the Four DAAs for the Patients at Issue, including but not limited to rebates, discounts, and other reductions to the costs ultimately incurred by TennCare for the drugs.

Response: OBJECTION. The Request as phrased seeks the production of documents outside of the relevant timeframe, and therefore is unduly burdensome and disproportionate to the needs of this case. Moreover, documentation pertaining to the "rebates, discounts, and other reductions to the costs ultimately incurred by TennCare" is irrelevant to the issues of this case.

Plaintiffs further object to this Request to the extent that it seeks documents or information that is deemed confidential under 42 U.S.C. § 1396r-8(b)(3)(D), Tenn. Code Ann. §§ 71-5-142 and -197(d), and the terms of state and federal rebate agreements. Without waiving this Objection, and pursuant to the applicable provisions of the Tennessee supplemental rebate agreements previously produced (TN-TEMP019431 through 019500), the State will notify the manufacturers of the Four DAAs at issue, and—absent an objection from such manufacturers—will produce responsive data for the relevant time period (Q4 2014 through Q2 2016) that is not otherwise subject to 42 U.S.C. § 1396r-8(b)(3)(D). Such data should be considered CONFIDENTIAL pursuant to the Protective Order entered in this action.

32. For the period between January 1, 2010 and the present, all documents and communications relating to any rebate agreement between HHS and any pharmaceutical manufacturer related to any of the Four DAAs, to any of the Other DAAs, and/or to any of the Non-DAAs.

Response: OBJECTION. The Request as phrased seeks the production of documents outside of the relevant timeframe and pertains to drugs not at issue in this case, and therefore is unduly burdensome, disproportionate to the needs of this case and seeks irrelevant information. Moreover, documentation pertaining to rebate agreements between HHS and pharmaceutical manufacturers is irrelevant to the issues of this case. The United States further objects to this request to the extent that it seeks documents or information that is confidential and may not be disclosed under 42 U.S.C. § 1396r-8(b)(3)(D). Without waiving this Objection, the United States responds that CMS has rebate agreements with manufacturers that cover all of a manufacturer's covered outpatient drugs (not just specific drugs). The standard terms of the template rebate agreement can be found in the addendum to the final notice published in the Federal Register at 83 FR 12770 (https://www.federalregister.gov/documents/2018/03/23/2018-05947/medicaid-program-announcement-of-medicaid-drug-rebate-program-national-rebate-agreement).

33. For the period between January 1, 2010 and the present, all documents sufficient to identify any other Pricing Arrangements between either Plaintiff and any pharmaceutical manufacturer related to any of the Four DAAs, to all Other DAAs, and/or to all Non-DAAs.

Response: OBJECTION. The Request as phrased seeks the production of documents outside of the relevant timeframe, and therefore is unduly burdensome and disproportionate to the needs of this case. Moreover, to the extent that the Request seeks information pertaining to "all Other DAAs, and/or to all Non-DAAs," the Request seeks information that is irrelevant to the issues of this case. Without waiving this Objection, the State of Tennessee previously has produced supplemental rebate agreements responsive to this Request for the relevant timeframe,

regarding the Four DAAs at issue. *See* TN-TEMP019431 through 019500 (which should be considered CONFIDENTIAL pursuant to the Protective Order entered in this action). The State and CMS have no other pricing arrangements aside from the rebate agreements referenced in Response No. 32, and the supplemental rebate agreements previously produced by the State.

34. For the period between January 1, 2010 and the present, all communications between TennCare and/or HHS, on the one hand, and any pharmaceutical manufacturer, on the other hand, relating to any and all significant, clinically meaningful therapeutic advantages of any of the Four DAAs over any other Hepatitis C Medication included on the TennCare Preferred Drug List.

Response: OBJECTION. The Request as phrased seeks the production of documents outside of the relevant timeframe, and therefore is unduly burdensome and disproportionate to the needs of this case. Moreover, the Request as phrased pertains only to compliance with 42 U.S.C. § 1396r–8(d)(4)(C)—a provision from which TennCare has been granted exemption by CMS pursuant to the Waiver granted in accordance with 42 U.S.C. § 1315. Accordingly, the information sought is wholly irrelevant to the issues of this case. Without waiving this Objection, TennCare has not located any documents responsive to this Request apart from the TennCare Pharmacy Advisory Committee meeting minutes previously produced.

35. For the period between January 1, 2010 and the present, all communications between TennCare and/or HHS, on the one hand, and any pharmaceutical manufacturer, on the other hand, relating to access to any of the Four DAAs by TennCare enrollees, including but not limited to any restrictions on such access imposed by TennCare.

Response: OBJECTION. The Request as phrased seeks the production of documents outside of the relevant timeframe, and therefore is unduly burdensome and disproportionate to the needs of this case. Moreover, the Request as phrased pertains only to issues addressed in CMS Medicaid Drug Rebate Program Notice, Release No. 172. However, as attested by John M. Coster, Director, Division of Pharmacy for the CMS, Release No. 172 was a "guidance" release which neither mandated any specific action nor invalidated any criteria. *See* Doc. 42-12. Moreover, as attested by Mr. Coster, CMS was aware of the prior authorization and utilization management criteria of Tennessee and other States, and did not invalidate such criteria, direct any State (including Tennessee) to stop using its criteria, or take any enforcement action against Tennessee or any other State. Accordingly, the information sought is wholly irrelevant to the issues of this case. Without waiving this Objection, TennCare has not located any documents responsive to this

Request. The United States does not believe that it would have any responsive communications because manufacturers do not normally identify specific states in communications with CMS.

36. All communications between you, on the one hand, and any pharmaceutical manufacturer, on the other hand, concerning this Action.

Response: Neither the United States, nor the State of Tennessee, have located any documents responsive to this Request.

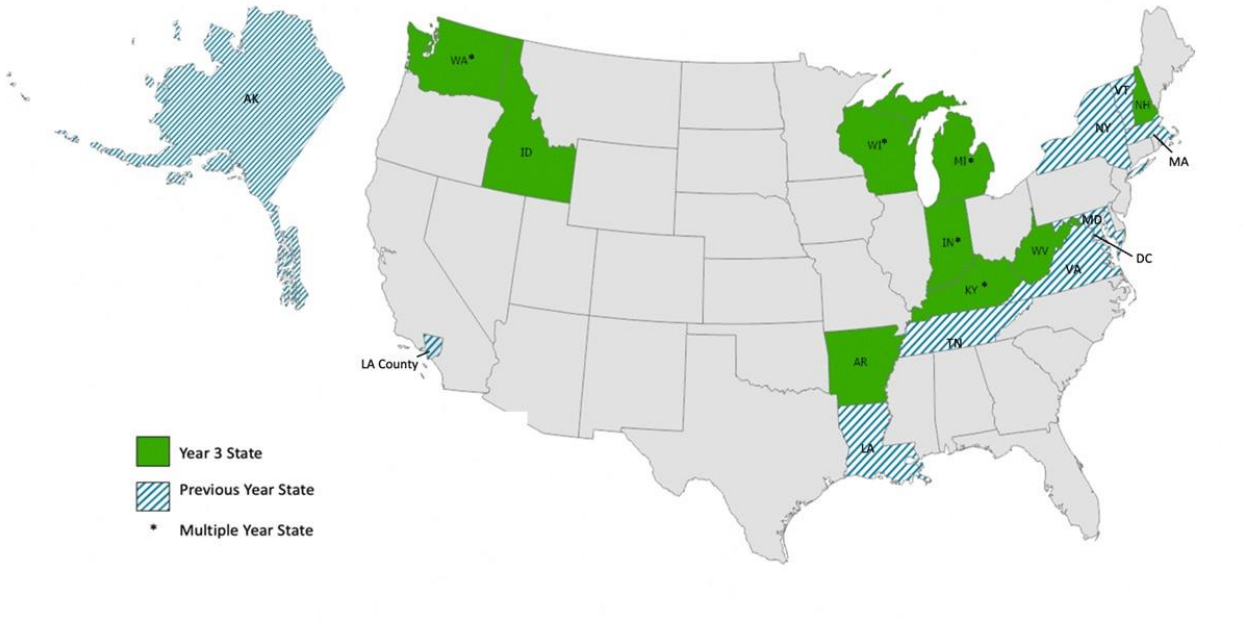
37. All documents relating to the Hepatitis C Medicaid Affinity Group, including but not limited to the following: documents relating to the group's formation, purpose, and activities; documents relating to criteria for joining and/or participating in the group; and documents sufficient to identify individual participants in the group.

Response: OBJECTION. The Request as phrased seeks the production of documents which are wholly irrelevant to the issues of this case. Moreover, the Request as phrased is overly broad and unduly burdensome in that it seeks "all documents relating to the Hepatitis C Medicaid Affinity Group." Many documents responsive to this Request are publicly available, and Defendant is further referred to https://www.hhs.gov/hepatitis/hepatitis-c-medicaid-affinity-group/index.html. Without waiving this Objection, Defendant is directed to TN-TEMP008278 through 008280 for identification of Tennessee employees who participated in the Hepatitis C Medicaid Affinity Group (MAG). Additional documents shall be produced, and Plaintiffs reserve the right to supplement their response to this Request.

38. All documents relating to Plaintiff the State of Tennessee's participation in the Hepatitis C Medicaid Affinity Group, including but not limited to the following: documents sufficient to identify persons who participated in the group on behalf of Tennessee; documents relating to any activities by or involving the group and related to Tennessee; any reports or other documents created by or for the group and related to Tennessee; and all communications between and among participants in the group and relating to Tennessee.

Response: OBJECTION. The Request as phrased seeks the production of documents which are wholly irrelevant to the issues of this case. Without waiving this Objection, *see* response to Request #37 above. Responsive documents may include these at the Affinity Group web page, including: https://www.hhs.gov/sites/default/files/HCV-Affinity-Group-Eval-Summary-Years-1-2.pdf; and https://www.hhs.gov/sites/default/files/TN-NewDawnofCollaboration-020719.pdf.

39. All documents relating to Plaintiff the State of Tennessee's status as a "Previous Year State" participant in the Hepatitis C Medicaid Affinity Group, as denoted in the following map appearing on the current homepage of the group.



Response: OBJECTION. The Request as phrased seeks the production of documents which are wholly irrelevant to the issues of this case. Without waiving this Objection, *see* response to Request #37 above.

40. All documents relating to any efforts undertaken by the Hepatitis C Medicaid Affinity Group to increase access by TennCare beneficiaries to the Four DAAs or to Other DAAs.

Response: OBJECTION. The Request as phrased seeks the production of documents which are wholly irrelevant to the issues of this case. Without waiving this Objection, the State of Tennessee has no such documents. The United States directs Defendant to the documents and information available at the Affinity Group webpage, and specifically to the stated purpose of

"bringing states together to support developing and implementing innovative strategies for scaling up HCV screening, treatment, and cure" through by providing opportunities for participating states "to share effective strategies and collaborate to identify solutions to common challenges." As such, the Hepatitis C Medicaid Affinity Group did not, as an entity, undertake specific efforts to increase access for Medicaid beneficiaries in specific states, but rather served as a resource to states to develop and implement their own initiatives. Accordingly, the United States does not believe that it possesses any responsive documents beyond what is available on the Affinity Group webpage. To the extent that any other responsive documents are identified in the course of discovery, this Response will be supplemented.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 8th day of December, 2021, a copy of the foregoing was served via email to the following:

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